The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
Board of Registration in Pharmacy
Investigative Report

In the Matters of:

1. **PHA-2013-0029 Royal Palm Specialty Pharmacy (DS89765; Issued 04/29/11)**
2. **PHA-2013-0040 Katie Fafalla (PH26808; Issued 09/05/2006)**

Current Manger of Record (MOR):

1. **Katie Fafalla 09/11/2012-present**
   (PH26808; Issued 09/05/2006)

Former Mangers of Record:

1. **Karen A. Blakely 08/10/2011-09/11/2012**
   (PH21868; Issued 10/08/92)
   (Formerly Karen Blackmar and Karen Chesanek)

2. **Agnes S. Rubin 05/25/11-08/10/11**
   (PH25022; Issued 04/20/01)
   (Formerly Agnes Bergeron and Agnes Kokosinski)

Inspection January 15, 2013:

1. Leo A. McKenna, PharmD, Quality Assurance Coordinator
2. Cheryl Lathum, PharmD, BCPS, Investigator
3. Allan C. Anderson, PharmD
4. Heather Engman, Counsel to the Board of Registration in Pharmacy

Allegation of Complaint: give nature code and summarize the allegations:

On January 15, 2013, an inspection was conducted at Royal Palm Specialty Pharmacy (DS89765; Issued 04/29/11), located at 118 Main Street in Webster, MA 01570. Quality Assurance Coordinator Leo McKenna, PharmD, Investigator Cheryl Lathum, PharmD, and Alan Anderson, PharmD participated in the inspection. Board Counsel Heather Engman was also on site.

Royal Palm Specialty Pharmacy has one OPEN complaint as follows:
PHA-2011-0309 QRE Pending Prosecution.

The current Manager of Record (MOR) Katie Fafalla (PH26808; Issued 09/05/2006; no prior complaints) was present for the entire inspection. Pharmacist Mark Rubin was present for the majority of the inspection. Pharmacist (and owner) Agnes Rubin was also present for part of the inspection.

Pharmacist Mark J. Rubin (PH 233459; Issued 04/20/11) has one OPEN complaint as follows:

1. PHA-2012-0005 QRE Pending Prosecution.

Pharmacist Agnes S. Rubin (PH25022; Issued 04/20/01) has one OPEN complaint as follows:

PHA-2012-0006 QRE Pending Prosecution.

Board investigators observed violations of Board regulations pertaining to the practice of pharmacy, including:

1. Registrant failed to comply with United States Pharmacopoeia (USP) Compounding Standards 795, in violation of 247 CMR 9.01(3);
2. Registrant failed to provide for an arrangement and storage of drugs that is calculated to prevent their accidental misuse, in violation of 247 CMR 6.01 (5) (b); and
3. Registrant failed to comply with 247 CMR 9.01(13) by providing practitioners with prescription blanks that refer to Royal Palm Pharmacy.

A 795 (non-sterile) compliance audit was conducted by Allan C. Anderson, PharmD. Please refer to *"Compounding Audit"* for Royal Palm Specialty Pharmacy. The following concerns were noted:

1. The pharmacy did not meet requirements for the storage and disposal of hazardous compounds. Investigators observed that hazardous drugs were stored in a common open environment that could potentially cause area contamination. In addition, investigators observed bottles of acids and bases stored in locations that are easily disrupted and not stored appropriately to protect the environment from contamination.
2. The pharmacy was unable to provide a policy, specific to their practice, which requires validation of new or changed facilities, equipment, processes, container types for sterility and repeatability.
3. The pharmacy was unable to provide a Standard Operating Procedure (SOP) to promptly address equipment problems.
4. The pharmacy was unable to provide a Standard Operating Procedure (SOP) to determine action and alert limits for environmental monitoring.
5. The pharmacy was unable to provide a Standard Operating Procedure (SOP) to develop and implement methods for improving quality based on analyzed data.
6. The pharmacy was unable to provide documentation of didactic training, visual process validation, or written assessment of personnel.
7. The pharmacy was unable to provide documentation that personnel who compound hazardous drugs are fully trained in the storage, handling, and disposal of hazardous drugs.
8. The pharmacy was unable to provide documentation that personnel receive training <u>prior</u> to preparing and handling hazardous drugs and that it is verified by testing specific hazardous drug preparation techniques.
9. The pharmacy was unable to provide documentation that personnel receive <u>annual</u> training and testing specific to hazardous drugs.
10. The pharmacy was unable to provide documentation that the annual training includes overview of the mutagenic, teratogenic, and carcinogenic properties of hazardous drugs.

11. The pharmacy was unable to provide documentation that personnel receive ongoing training for each new hazardous drug that enters the marketplace.
12. The pharmacy was unable to provide documentation that personnel of reproductive capability confirm in writing that they understand the risks of handling hazardous drugs as part of the orientation process and on an annual basis.
13. The pharmacy was unable to provide documentation that the pharmacy maintains results of quality control procedures (i.e. weight range of filled capsules, pH of aqueous liquids).
14. The pharmacy was unable to provide documentation that the compounding record contains information about quality control issues, adverse reactions, or preparation problems.
15. The pharmacy was unable to provide a Standard Operating Procedure (SOP) describing procedures to prevent cross-contamination.
16. The pharmacy was unable to provide a Standard Operating Procedure (SOP) to appropriately handle, clean, and store equipment used for allergenic ingredients.
17. The pharmacy was unable to provide a Standard Operating Procedure (SOP) describing processes that ensure extra care for cleaning of equipment and tools used for hazardous compounding.
18. The pharmacy was unable to provide a Standard Operating Procedure (SOP) describing the dedication of equipment for hazardous compounding for such use.
19. The pharmacy was unable to provide Standard Operating Procedures for all significant procedures performed in the compounding area.
20. The pharmacy was unable to provide Standard Operating Procedures to ensure accountability, accuracy, quality, safety, and uniformity in compounding.
21. The pharmacy was unable to provide quality control history and quality assurance trend reports.
22. Pharmacy personnel were unable to locate the MSDS file (Material safety Data Sheets).
23. The pharmacy was unable to provide a Standard Operating Procedure (SOP) to ensure that preparations leaving the site retain their integrity and stability through the shipping cycle.
24. The pharmacy was unable to provide a Standard Operating Procedure (SOP) and provide documentation that the compounding record contains a duplicate label as described in the master formulation record.
25. The pharmacy was unable to document that the compounding record contains the sources, lot numbers, and expiration dates of compounds.
26. The pharmacy was unable to document that the compounding record contains the description of the final preparation.
27. The pharmacy was unable to document that the compounding record contains the results of quality control procedures.

During an inspection on April 24, 2012, the plan-of-correction (POC) to Docket PHA-2012-0309 was reviewed with pharmacist Mark J. Rubin and (former) Manager of Record Karen Blakely. The plan of correction stated that the pharmacy would promptly label the bulk liothyronine bottle with "trituration only" (i.e. to be diluted to a 1:1000 powder). On April 24,

2012 Investigator Lathum requested to observe the storage of the bulk liothyronine in the refrigerator. Investigator Lathum observed a bottle of liothyronine sodium 500 mg, **not** labeled as "trituration only", stored in close proximity to T3 (liothyronine) 1:1000 trituration and T-4 (levothyroxine) 1:1000 trituration.

In response to the April 24, 2012 inspection Royal Palm Specialty Pharmacy submitted a plan-of-correction on April 26, 2012 that in part created a "Checklist for Safety and Efficiency" that will be reviewed weekly by an assigned employee. The check list included verifying that "For Trituration Only" is clearly labeled on any bag /bin, containing any applicable medication (such as liothyronine sodium 500 mg).

On January 15, 2013, Investigator Lathum observed a bottle of liothyronine sodium 1 gram, **not** labeled as "trituration only", stored in the refrigerator.

On October 25, 2012, the pharmacy voluntarily ceased all sterile compounding. Investigator Lathum observed that Royal Palm Specialty Pharmacy was dispensing HCG 11,000 IU and GHRP-6 injection, compounded prior to October 25, 2012. Investigator Lathum requested that all HCG and GHRP-6 be returned to an authorized vendor.

Per 247 CMR 9.01 (13), "A pharmacist, pharmacy, pharmacy department, pharmaceutical organization or pharmacy corporation shall not provide any practitioner with prescription blanks which refer to any pharmacist, pharmacy or pharmacy department." Investigators observed prescription order forms for HCG which contained the name "Royal Palm Compounding Pharmacy" and the pharmacy's logo (mortar with a palm tree pestle). (Royal Palm Compounding Pharmacy and Royal Palm Specialty Pharmacy's logos appear to be identical.) The HCG prescription order forms also contained the fax number for Royal Palm Specialty Pharmacy in Massachusetts. Investigators also observed a prescription for ketoprofen/gabapentin/cyclobenazaprine/lidocaine) which contained the pharmacy's logo.

Of note, Royal Palm Compounding Pharmacy was a pharmacy located in Florida owned by Mark Rubin. Royal Palm Specialty Pharmacy is located in Massachusetts and is owned by Agnes Rubin.

Investigator Lathum reviewed 16 CFR 1700 poison prevention packaging requirements with MOR Fafalla. Per 247 CMR 6.07, "(1) The responsibilities of the pharmacist Manager of Record shall include, but may not be limited, to the following:(c) the maintenance at all times of adequate pharmacy and pharmacy department security consistent Board regulations at 247 CMR 2.00 *et seq.*, and all other applicable state and federal laws and regulations"

Per MOR Fafalla, no patients have requested non-safety caps (i.e. noncompliance packaging) at Royal Palm Specialty Pharmacy. However, MOR Fafala implemented a new log to capture written requests for non-safety caps.

Plan of Correction (POC)

A plan-of-correction was received by the Office of Public Protection on January 28, 2013 via e-mail; a hard copy was received on January 30, 2013. The plan-of correction is as follows:

1. The "Checklist for Safety and Efficiency" was updated to include a check of the whole refrigerator to confirm no raw T3/T4 exists outside of the "for trituration" bin. The checklist includes a place for both a technician and pharmacist to initial.
2. A new daily checklist was implemented to document that daily refrigerator temperatures are being monitored.
3. The labeled bins for T-3 trituration and T-4 trituration were placed in separate locations in the refrigerator.
4. A new sign was placed on the "for trituration" bin.
5. Training for pharmacy personnel was initiated about the difference between T3 and T4.
6. A new Standard Operating procedure (SOP) was developed (SOP 9.18 T3/T4 Storage).
7. An area in the clean room was designated for storage of hazardous substances. This room has a negative pressure. A sign was posted on the door stating, "hazardous Chemicals: Authorized Personnel Only."
8. Training for pharmacy personnel was initiated about the storage and handling of hazardous substances, including location of the MSDS.
9. Updated SOPs 7.010, 7.020, 7.030 and 9.160.
10. Created new employee handouts about The Effects of Workplace Hazards on female and Male Reproductive Health.
11. Implemented an annual attestation to be signed by women of childbearing age and men of reproductive capability.
12. Returned injectable HCG and GHRP-6 to an appropriate vendor.
13. Updated SOP 9.160 to include separation of acids and bases.
14. Updated SOP 9.010 to include testing of 4 random compounded preparations per month. Data will be tracked and analyzed.
15. Updated SOP 9.010 to include test weight, volumes and pH's for different compounded preparations.

Investigator Signature: _____ **Date:** 05/07/13

Supervisor Signature: _____ **Date:** 5/7/13